

Appl. No. 09/877,374

Reply to Office action of March 18, 2008

REMARKS/ARGUMENTS

Claims 1 to 5, 9 to 29, 62 to 70, 72, 74 and 75 are pending in this application. Claims 6 to 8, 30 to 61, 71 and 73 have been previously canceled. New claims 74 and 75 have been added and are supported for example, at page 71, lines 8 to 11 where it is discussed that the magnum portion of the oviduct is minced and enzymatically disassociated in preparation for transfection. This amendment includes no new matter.

The Examiner rejects claims 1 to 5, 9 to 17, 19 to 29, 62 and 63 under 35 USC 103(a) as being obvious over Dutillo when taken with Sanders and in further view of Mohammed and in further view of Michael. Applicant has shown that it has been determined that monoclonal antibodies produced in avian oviduct cells and deposited into eggs are not fucosylated citing Table 2 at page 1162 of Zhu et al, Nature Biotechnology (2005) vol 23, p 1159-1169. Applicant has pointed out that this lack of fucosylation in the oviduct cells of chickens is in contrast to what is seen in other cells of the chicken as seen in Graph A of Fig. 4 at page 483 of Raju et al (2000) vol 10, p 477-486. Applicant has also pointed out that this absence of fucose alters the therapeutic utility of monoclonal antibodies by increasing their potency which is shown, for example, at the first column, last paragraph of page 102 of Etches, Trends in Biotechnology (2006) vol 24, p101-102.

As stated in applicant's Response filed 2/15/08, quoting from *KSR International Co. V. Teleflex Inc. Et Al.* in *Ex parte Smith* the question is "whether the improvement is more than the predictable use of prior-art elements according to their established functions" and accordingly the present invention is not obvious because of at least one advantageous characteristic of the claimed invention not particularized in the prior art references.

The Examiner has responded to applicant in the first and second full paragraphs at page 3 of the paper mailed 3/18/08 (hereon referred to as Office Action) stating that both Zhu and Etches are post filing art and therefore are not pertinent to the art at the time of filing. The Examiner indicates that 35 USC 103 requires that post filing evidence of patentability be pertinent to art at the time of filing and cites language from section 103 which states the legal parameters for a finding that a claimed invention is obvious, underlining an excerpt that states "at the time the invention was made". Apparently the

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Examiner is attempting to draw a nexus between language dictating the requirements for a finding of obviousness and what is required for a showing of an improvement that is more than the predictable use of prior art elements according to their established function. In other words the Examiner is improperly attempting to use requirements for an affirmative showing of obviousness to prevent applicant from submitting post filing evidence of non-obviousness which was published after filing of the application. The Examiner provides no legal support to make such a connection or to use the statutory language in this way. Accordingly, post filing evidence of patentability provided in Zhu and Etches has been properly submitted.

In the third full paragraph at page 3 of the Office Action the Examiner indicates that there is no support in the application for the feature of a lack of fucosylation and that the increased potency of monoclonal antibodies was not known at the time of the claimed invention. The Examiner also states that there is nothing in the claims that requires an antibody with increased potency. First, the requirements regarding what must be disclosed in a specification to properly describe an invention are found in the Written Description and Enablement requirements of 35 USC 112. These requirements have been fulfilled by applicant. The Examiner appears to be attempting to improperly add new requirements to what an adequate disclosure for an invention is. Disclosing all of the features such as all advantages of an invention is not a requirement for patentability. In addition, there is no requirement that the advantageous features of an invention be present in the claims or, as in this case, that advantageous features of the product which is produced by a method be specified in a method claim. Furthermore, KSR does not state that the improvement which is more than the predictable use of prior art elements according to their established function need be disclosed in the application or need to be specified in the claims.

In the paragraph beginning at the bottom of page 3 and spanning to the top of page 4 of the Office action the Examiner cites Raju indicating that in Raju there is no mention that a lack of fucosylation would produce more potent antibodies or that an avian oviduct cell such as a tubular gland cell would not produce an antibody. The Examiner further states that Raju provides no guidance to show that there would be any unpredictability in producing monoclonal antibodies in avian oviduct cells and that Raju

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is not relevant to the instant invention because Raju generally discusses fucosylation of IgGs from chickens, but does not discuss production of a heterologous antibody from specific chicken cells. Applicant's point in presenting Raju is that antibodies produced in the serum of chickens were known at the time of the invention to contain fucose. This is evidence that it was unexpected (i.e., unpredictability) that antibodies produced in certain cells in a chicken such as oviduct cells would not contain fucose.

The Examiner also notes that obviousness can be established in the prior art even if the reasons to modify the references are different and cites MPEP 2144. Applicant does not believe the section of MPEP 2144 cited by the Examiner relates to applicant's non-obviousness argument presented in applicant's paper of 2/15/08. The Examiner continues stating that the claimed invention is obvious citing Ditullio, Sanders, Mohammed and Michael. The Examiner also points out that claim 18 has been rejected over Ditullio when taken with Sanders, in further view of Mohammed, and in further view of Michael as applied to claims 1-5, 9-17, 19-29, 62 and 63 above, and further in view of Larocca and that claims 64-70 and 72 have been rejected over Ditullio when taken with Sanders, in further view of Mohammed, and further in view of Michael as applied to claims 1-5, 9-17, 19-29, 62 and 63 and further in view of Ling and Najarfian.

As applicant has stated, the improvement of producing monoclonal antibodies in oviduct cells in culture is more than the predictable use of prior art elements according to their established function since for one thing the increased potency of the monoclonal antibodies produced could not be predicted based upon the prior art. Therefore, in accordance with the Supreme Court ruling in *KSR*, the obviousness rejections are improper and should be withdrawn.

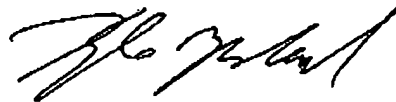
In conclusion, applicant has shown that the claims 1 to 5, 9 to 29, 62 to 70, 72, 74 and 75 are allowable and requests the Examiner to pass the above-identified application to allowance.

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If any issues remain to be addressed in this matter, which might be resolved by discussion, the Examiner is respectfully requested to call applicants' undersigned counsel at the number indicated below.

Respectfully submitted,



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